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IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

ARAGON PHARMACEUTICALS, INC., JANSSEN BIOTECH, INC., and SLOAN-KETTERING INSTITUTE FOR CANCER RESEARCH,

Plaintiffs,

v.

ZYDUS WORLDWIDE DMCC, ZYDUS PHARMACEUTICALS (USA) INC., and ZYDUS LIFESCIENCES LIMITED,

Defendants.

ARAGON PHARMACEUTICALS, INC., JANSSEN BIOTECH, INC., and THE REGENTS OF THE UNIVERSITY OF CALIFORNIA,

Plaintiffs,

v.

ZYDUS WORLDWIDE DMCC, ZYDUS PHARMACEUTICALS (USA) INC., and ZYDUS LIFESCIENCES LIMITED,

Defendants.

Honorable Stanley R. Chesler, U.S.D.J.

Civil Action No. 2:22-CV-02964(SRC)(LDW) Consolidated

Honorable Stanley R. Chesler, U.S.D.J.

Civil Action No. 2:23-CV-01685 (SRC)(LDW)

CONSENT JUDGMENT AND ORDER

WHEREAS Civil Action No. 2:23-cv-01685 (SRC)(LDW) has been brought by Aragon Pharmaceuticals, Inc., Janssen Biotech, Inc., and The Regents of the University of California against Zydus Worldwide DMCC, Zydus Pharmaceuticals (USA) Inc., and Zydus

Lifesciences Limited (collectively, "Zydus") alleging infringement of United States Patent Nos. 8,445,507, 8,802,689, 9,388,159, and 9,987,261 (collectively, the "Patents-in-Suit");

WHEREAS Civil Action No. 2:23-cv-01685 (SRC)(LDW) was consolidated under 2:22-cv-02964 (SRC)(LDW) which included Plaintiffs Aragon Pharmaceuticals, Inc., Janssen Biotech, Inc., and Sloan-Kettering Institute for Cancer Research (along with The Regents of the University of California, "Plaintiffs");

WHEREAS Plaintiffs currently market in the United States pursuant to New Drug Application No. 210951, a drug product containing Apalutamide under the trade name ERLEADA® ("Erleada Product");

WHEREAS Zydus Worldwide DMCC filed or caused to be filed Abbreviated New Drug Application ("ANDA") No. 217113 seeking FDA approval to make, sell, offer for sale, use and/or import in or for the United States a pharmaceutical product asserted to be bioequivalent to the Erleada Product in such ANDA No. 217113 ("Zydus ANDA Product");

WHEREAS Plaintiffs and Zydus have resolved this litigation for the Patents-in-Suit as to Zydus for good cause and valuable consideration recognized by Plaintiffs and Zydus;

WHEREAS Plaintiffs and Zydus respectfully request that the Court terminate the pending litigation as between Plaintiffs and Zydus by the entry of this Judgment and Order; and WHEREAS Plaintiffs and Zydus now consent to this Judgment and Order.

IT IS ORDERED, ADJUDGED AND DECREED as follows:

- 1. This District Court has jurisdiction over the subject matter of the above action and has personal jurisdiction over the parties.
- 2. Zydus admits that the claims of the Patents-in-Suit are valid and enforceable solely with respect to products containing Apalutamide (the active pharmaceutical

ingredient in the Zydus ANDA Product) as the sole active ingredient that are sold, offered for sale or distributed under an Abbreviated New Drug Application that refers to the product sold pursuant to NDA No. 210951 as the reference-listed drug, and that the claims of the Patents-in-Suit would be infringed by the commercial manufacture, use, sale, offer for sale, or importation of the Zydus ANDA Product in the United States prior to the expiration of the Patents-in-Suit.

- 3. Zydus and its affiliates are hereby enjoined from manufacturing, using, offering for sale, selling in the United States, or importing into the United States, the Zydus ANDA Product until the expiration of the Patents-in-Suit, including any patent term extensions and/or patent term adjustments and during the period of any associated pediatric exclusivity, other than as authorized by Plaintiffs.
- 4. All affirmative defenses, claims and counterclaims, which have been or could have been raised by Plaintiffs against Zydus and its affiliates, or by Zydus and its affiliates against Plaintiffs, in this litigation solely with respect to the Patents-in-Suit as asserted against the Zydus ANDA Product are hereby dismissed with prejudice.
- 5. Plaintiffs and Zydus shall bear their own fees and costs in connection with this litigation, including attorneys' fees.
- 6. Plaintiffs and Zydus waive all right to appeal or otherwise move for relief from this Judgment and Order.
- 7. This Court shall retain jurisdiction of this litigation and over Plaintiffs and Zydus for purposes of enforcement of the provisions of this Judgment and Order.

IT IS SO ORDERED this _____ day of ____ December 2024 Document 130

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s/ Stanley R. Chesler

HONORABLE STANLEY R. CHESLER UNITED STATES DISTRICT JUDGE

Dated: November 27, 2024

We hereby consent to the form and entry of this Order:

s/ Keith J. Miller

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